

Medical devices

2012/0266(COD) - 05/04/2017 - Final act

PURPOSE: to ensure the proper functioning of the internal market with regards to medical devices and to improve the safety of medical devices for the benefit of patients.

LEGISLATIVE ACT: Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

CONTENT: the Regulation establishes **rules concerning the placing on the market of medical devices for human use** and accessories for such devices in the Union. It also applies to **clinical investigations** concerning such medical devices and accessories conducted in the Union.

It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer adequate to regulate the sector.

Its objective is to enhance patient safety by: (i) introducing more stringent procedures for conformity assessment and for post-marketing surveillance, and (ii) requiring manufacturers to produce clinical safety data, performance and unknown side-effects.

The Regulation will also apply as from the date of application of common specifications (CS), to the **groups of products without an intended medical purpose** such as contact lenses, equipment for liposuction, lipolysis or lipoplasty.

Notified bodies: the Regulation strengthens the provisions on the **designation, organisation, monitoring and expertise** of the independent notified bodies, which conduct the assessment for medical devices before they are placed on the market and it strengthens monitoring by national authorities of notified bodies. The new rules also ensure that notified bodies meet the **same high safety standards** throughout the EU. Notified bodies must have sufficient administrative, technical and scientific personnel for them to successfully conduct their conformity assessment activities. **On-site audits, including unannounced visits**, must be carried out.

Availability of clinical data: the requirements on collection of data in clinical investigations on medical devices have been specified and aligned to those applicable for clinical trials on medicinal products for human use, particularly as regards provisions on informed consent and protection of vulnerable subjects (e. g. incapacitated subjects, minors, pregnant women.)

There is a **special procedure** involving an independent assessment carried out by a special expert panel of the highest risk devices.

Obligations of manufacturers : the Regulation sets out the obligations of manufacturers regarding monitoring the quality, performance and safety of devices placed on the market.

Manufacturers should, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide:

- sufficient financial coverage in respect of their potential liability under [Directive 85/374/EEC](#);
- a system regarding the monitoring of quality and a post-market surveillance system.

The **authorised representative** would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices.

The Regulation also requires Member States to take the measures necessary to allow health professionals, users and patients to **report suspected serious incidents** at national level using harmonised formats.

Identification and traceability of devices: in order to ensure that measures may be taken quickly if problems arise, the Regulation contains provisions regarding the registration of devices and of economic operators as well as detailed rules to ensure the traceability of medical devices right through the supply chain up to the end user or patient, thanks to the establishment of a **Unique Device Identification (UDI) System**.

Storage of the UDI code by health institutions and economic operators is mandatory for class III implantable devices.

Use of hazardous substances in invasive medical devices: manufacturers must provide a justification to the notified body regarding the presence of substances that are **carcinogenic, mutagenic or toxic to reproduction and/ or endocrine** disruptors above a certain concentration in invasive medical devices and devices that transport and store medicinal products, or other substances to be (re) administered into or removed from the body.

Single use devices: the reprocessing of single use devices may only take place if allowed under national law, and in conformity with the provisions of the Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers. However, in certain circumstances, Member States may provide for derogations to the rules in the case of reprocessing of medical devices by health institutions.

European Databank on Medical Devices ('EUDAMED'): the Regulation establishes a central data bank aimed at providing patients, health professionals and the public with full information on the products available in the EU, which will enable them to take decisions more easily.

ENTRY INTO FORCE: 25.5.2017.

APPLICATION: from 26.5.2020.

DELEGATED ACTS: the Commission may adopt delegated acts to amend non-essential elements of the Regulation. The power to adopt such acts is conferred on the Commission for a period of five years (renewable) from 25 May 2017. The European Parliament or the Council have the right to object to a delegated act within three months (which may be extended by three months) from the date of notification of the act.